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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/688,858	10/17/2003	Daniel L. Dunn	069090.1	9455

25763 7590 12/09/2008

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EXAMINER	
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ART UNIT	PAPER NUMBER
3686	

MAIL DATE	DELIVERY MODE
12/09/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/688,858
Filing Date: October 17, 2003
Appellant(s): DUNN ET AL.

Adriana S. Luedke
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 26 June 2007 appealing from the Office action mailed 28 November 2006.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is substantially correct. The changes are as follows: appellant's statement of the grounds

of rejection to be reviewed on appeal does not include the New Grounds of rejection, which has been added, and is set forth both here and in Section (9) of this examiner's answer.

NEW GROUND(S) OF REJECTION

The following new ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 101

1. 35 U.S.C. § 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. Claims 1-10 are rejected under 35 U.S.C. §101 as being directed to non-statutory subject matter.

Based on Supreme Court precedent, and recent Federal Circuit decisions, the Office's guidance to examiners is that a § 101 process must (1) be tied to another statutory class (such as a particular apparatus) or (2) transform underlying subject matter (such as an article or materials) to a different state or thing. *Diamond v. Diehr,* 450 U.S. 175, 184 (1981); *Parker v. Flook*, 437 U.S. 584, 588 n.9 (1978); *Gottschalk v. Benson,* 409 U.S. 63, 70 (1972); *Cochrane v. Deener,* 94 U.S. 780,787-88 (1876).

An example of a method claim that would not qualify as a statutory process would be a claim that recited purely mental steps. Thus, to qualify as a § 101 statutory process, the claim should positively recite the other statutory class (the thing or product) to which it is tied, for example by identifying the apparatus that accomplishes the

method steps, or positively recite the subject matter that is being transformed, for example by identifying the material that is being changed to a different state.

In the instant application, Appellant's method steps, fail the first prong of the new Federal Circuit decision since they are not required to be tied to another statutory class and can be performed without the use of a particular apparatus. Furthermore, the method steps fail to unambiguously require transformation of underlying subject matter to a different state or thing. The mere manipulation and production of non-functional descriptive material is not a transformation because non-functional descriptive material is not statutory subject matter. Thus, method claims 1-10 are non-statutory since they are not requisitely tied to another statutory class and they do not requisitely transform underlying subject matter to a different state or thing.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

2004/0024620	Robertson	1-2003
2002/0188476	Bienvenu	6-2001

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

(New Grounds) Claim Rejections - 35 USC § 101

3. 35 U.S.C. § 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 1-10 are rejected under 35 U.S.C. §101 as being directed to non-statutory subject matter.

Based on Supreme Court precedent, and recent Federal Circuit decisions, the Office's guidance to examiners is that a § 101 process must (1) be tied to another statutory class (such as a particular apparatus) or (2) transform underlying subject matter (such as an article or materials) to a different state or thing. *Diamond v. Diehr,* 450 U.S. 175, 184 (1981); *Parker v. Flook*, 437 U.S. 584, 588 n.9 (1978); *Gottschalk v. Benson,* 409 U.S. 63, 70 (1972); *Cochrane v. Deener,* 94 U.S. 780,787-88 (1876).

An example of a method claim that would not qualify as a statutory process would be a claim that recited purely mental steps. Thus, to qualify as a § 101 statutory process, the claim should positively recite the other statutory class (the thing or product) to which it is tied, for example by identifying the apparatus that accomplishes the method steps, or positively recite the subject matter that is being transformed, for example by identifying the material that is being changed to a different state.

In the instant application, Appellant's method steps, fail the first prong of the new Federal Circuit decision since they are not required to be tied to another statutory class

and can be performed without the use of a particular apparatus. Furthermore, the method steps fail to unambiguously require transformation of underlying subject matter to a different state or thing. The mere manipulation and production of non-functional descriptive material is not a transformation because non-functional descriptive material is not statutory subject matter. Thus, method claims 1-10 are non-statutory since they are not requisitely tied to another statutory class and they do not requisitely transform underlying subject matter to a different state or thing.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-10 rejected under 35 U.S.C. 103(a) as being unpatentable over Robertson(2004/0024620) in view of Bienvenu(2002/0188476).

3. As per claim 1, Robertson teaches a method for assessing risk the method comprising (Robertson; Abstract):

receiving demographic data (Robertson; Pg. 2, Para. 27);

assigning the data to at least one risk group (Robertson; Pg. 4, Para. 64);

storing risk data for the patient (Robertson; Pg. 4, Para. 65);

calculating a risk score for the patient based upon the risk data and the demographic data of the patient (Robertson; Pg. 4, Para. 54).

Robertson does not expressly teach using prescription data for a patient. However this is well known in the art as evidenced by Bienvenu. In particular, Bienvenu teaches screening prescription history of an insurance applicant (Bienvenu; Pg. 1, Para. 17). It would have been obvious to add this feature to the Robertson method with the motivation of having an effective system and method for assessing prescription drug history information stored in the databases, processing the information and incorporating the information in the insurance process (Bienvenu; Pg. 1, Para. 7)

4. As per claims 2-9, Robertson teaches assigning data to at least one risk group and using risk marker's to calculate a risk score (Robertson; Pg. 2 Para. 27 and Pg. 4 Paras. 54 and 65). Robertson does not expressly teach using prescription data. However this is well known in the art as evidenced by Bienvenu. IN particular, Bienvenu teaches:

using national drug codes to classify each prescription. (Bienvenu; Fig. 5 and Pg. 5, Paras. 42 and 43);

categorizing each national drug code classification into one of a number of pharmacy risk groups (Bienvenu; Fig. 5 and Pg. 5, Paras. 42 and 43);

defining additional member risk markers based on patient age and other characteristics known to indicate that the patient belongs to a high risk category and using the additional member risk markers to calculate the patient's risk score. (Bienvenu; Pg. 1, Para. 4);

providing a clinical and demographic risk profile for the patient based on the patient's age, gender and a mix of clinical and demographic risk profiles and using the patient's clinical and demographic risk profile to calculate the patient's risk score (Bienvenu; Pg. 1, Para. 4 and Pg. 5, Para. 43).

providing multiple patient risk markers for patients with pharmacy services that indicate multiple medical conditions (Bienvenu; Fig. 5);

each risk group is assigned a numerical risk value based upon the patient's demographic data, and the patient's risk score is the sum of the numerical risk values of the risk groups in the patient's risk data (Bienvenu; Pg. 5; Para. 43);

wherein the risk score is computed using pre determined weights and a patient's patient risk marker profile (Bienvenu; Pg. 5, Para. 43);

wherein the pharmacy risk groups comprise patient risk markers (Bienvenu; Pg. 5, Para. 43).

It would have been obvious to add this feature to the Robertson method with the motivation of having an effective system and method for assessing prescription drug

history information stored in the databases, processing the information and incorporating the information in the insurance process (Bienvenu; Pg. 1, Para. 7)

Claim 10 repeats the limitations of claim 1 and the reasons for rejection are incorporated herein.

(10) Response to Argument

In the Appeal Brief filed 26 June 2007, Appellant make the following arguments:

A) Robertson explicitly teaches away from the use of demographic data to assess risk in the automotive insurance context.

B) There is no motivation to combine Robertson and Bienvenu

C) The suggested combination does not disclose the present invention as claimed in the independent claims, and particularly the following limitations:

1) assigning the prescription data for each prescription to at least one risk group based upon at least one medical condition typically treated by the prescription.

2) storing risk data for the patient, wherein the risk data includes the risk groups for all prescription data of the patient;

3) calculating a risk score for the patient based upon the risk data and the demographic data of the patient.

The Examiner will address the arguments in the order that they appear in the Appeal Brief.

Argument A:

In response to Appellant's first argument, Examiner respectfully submits that Robertson does *not* teach away from the use of demographic data to assess risk in the automotive insurance context. Robertson teaches using conventional risk classification (demographic data) in combination with using non-conventional risk classification methods (behavioral variables, personality traits) (Robertson; Pg. 2, para. 32). Robertson further goes on to say that these non-conventional methods need not be a replacement for the conventional risk classification methods. Appellant argues that Robertson neither teaches nor suggests the collection or use of demographic data in calculating risk and teaches away from the use of such information. However, Robertson (pg. 3, para. 51) clearly teaches collecting demographic data such as age, marital status and driving experience in addition to the survey answers. Thus, Robertson does not teach away from the use of demographic data. Robertson merely teaches that different techniques of risk classification, conventional and non-conventional, are known in the art and can be used together and neither as a replacement for the other.

Argument B:

In response to Appellant's second argument, Examiner respectfully submits there is sufficient motivation to combine Robertson with Bienvenu. Appellant argues that Examiner's motivation to combine reference was made with hindsight and that Robertson teaches a different methodology in the automobile context and has nothing to do with prescription data (Appeal Brief pg. 14). In response, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Both references deal with insurance and classifying and determining risk. Robertson deals with automobile insurance but one of ordinary skill in the insurance art would recognize the principles of risk classification are applicable to insurance in any context, including health care.

Furthermore in response to applicant's argument that Robertson is nonanalogous art (automobile insurance), it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24

USPQ2d 1443 (Fed. Cir. 1992). In this case, Robertson and the claimed invention deal with insurance and risk classification. The claimed invention is particularly concerned with assessing risk for insuring a health care patient. Robertson's teachings of specific risk classification techniques are reasonably pertinent for assessing risk in any field including health care.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Examiner believes that the cited motivation of "having an effective system and method for assessing prescription drug history information stored in the databases, processing the information and incorporating the information in the insurance process" (Bienvenu; Pg. 1, Para. 7) is sufficient. Examiner believes that one of ordinary skill in the art would be motivated to combine the Robertson risk classification techniques with the Bienvenu prescription history system in order to have an effective prescription drug history system for an insurer as taught by Bienvenu.

In addition, as discussed in the *KSR International Co. v. Teleflex Inc. et al.*, 127 S.Ct 1727 (2007), "[o]ften, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis should be made explicit. See *In re Kahn*, 441 F. 3d 977, 988 (CA Fed. 2006) ('[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness'). As our precedents make clear, however, the analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ" (emphasis added). One of ordinary skill in the art would be motivated to combine the teaching of Bienvenu and Robertson in order to have a complete system to insure risk of a healthcare patient. A person of ordinary skill in the art would be motivated to combine the Robertson risk classification techniques with the Bienvenu prescription history system in order to assess a healthcare patient's risk effectively and accurately. As stated earlier, both references deal with insuring risk thus the specific techniques in Robertson are pertinent to the Bienvenu system.

Argument C:

In response to Applicant's third argument, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Examiner submits that the combined teachings of Robertson and Bienvenu teach the claimed invention. Examiner will discuss the particular reasons below.

Applicant argues that the combined references do not teach assigning the prescription data for each prescription to at least one risk group based upon at least one medical condition typically treated by the prescription. Examiner disagrees. Robertson teaches assigning the data to at least one risk group (Robertson; Pg. 4, Para. 64). Examiner admits that Robertson does not teach assigning prescription data to a risk group but brings in the Bienvenu reference for that purpose. Bienvenu teaches collecting and screening prescription of prescription history data by Pharmacy Benefit Managers for insurers to determine risks of an insured individual (see Pg. 1, paras. 4-10). Thus, Robertson teaches the general risk classification technique and Bienvenu teaches the particular type of data (prescription history) to be incorporated with this technique. The motivation to combine these features is discussed above.

Next Applicant argues that the combined references do not teach storing risk data for the patient, wherein the risk data includes the risk groups for all prescription data of the patient and calculating a risk score for the patient based upon the risk data and the demographic data of the patient. Examiner disagrees. Robertson teaches the storing of risk data for the patient (Robertson; Pg. 4, Para. 65). Also, Robertson teaches calculating a risk score for the patient based upon the risk data and the demographic data of the patient (Robertson; Pg. 4, Para. 54). Again, Examiner submits one of ordinary skill in the art would combine the particular type of data (prescription history) taught by Bienvenu to the Robertson risk classification methodology.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

(12) Notice to Appellant – Reply is Required

This examiner's answer contains a new ground of rejection set forth in sections **(6)** and **(9)** above. Accordingly, appellant must within **TWO MONTHS** from the date of this answer exercise one of the following two options to avoid *sua sponte* **dismissal of the appeal** as to the claims subject to the new ground of rejection:

(1) **Reopen prosecution.** Request that prosecution be reopened before the primary examiner by filing a reply under 37 CFR 1.111 with or without amendment, affidavit or other evidence. Any amendment, affidavit or other evidence must be relevant to the new grounds of rejection. A request that complies with 37 CFR 41.39(b)(1) will be entered and considered. Any request that prosecution be reopened will be treated as a request to withdraw the appeal.

(2) **Maintain appeal.** Request that the appeal be maintained by filing a reply brief as set forth in 37 CFR 41.41. Such a reply brief must address each new ground of rejection as set forth in 37 CFR 41.37(c)(1)(vii) and should be in compliance with the other requirements of 37 CFR 41.37(c). If a reply brief filed pursuant to 37 CFR 41.39(b)(2) is accompanied by any amendment, affidavit or other evidence, it shall be treated as a request that prosecution be reopened before the primary examiner under 37 CFR 41.39(b)(1).

Extensions of time under 37 CFR 1.136(a) are not applicable to the TWO MONTH time period set forth above. See 37 CFR 1.136(b) for extensions of time to reply for patent applications and 37 CFR 1.550(c) for extensions of time to reply for ex parte reexamination proceedings.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

LLe for

LLe

12/8/2008

Gerald J. O'Connor
Supervisory Patent Examiner
Group Art Unit 3686

A Technology Center Director or designee must personally approve the new ground(s) of rejection set forth in section (9) above by signing below:

Wynn W. Coggins

Director, Technology Center 3600

Conferees:

Gerald J. O'Connor
Supervisory Patent Examiner
Group Art Unit 3686

for

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